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[Continued on next page]

(54) Title: ULTRASONIC VISUALIZATION OF PERCUTANEOUS NEEDLES, INTRAVASCULAR CATHETERS AND OTHER INVASIVE DEVICES

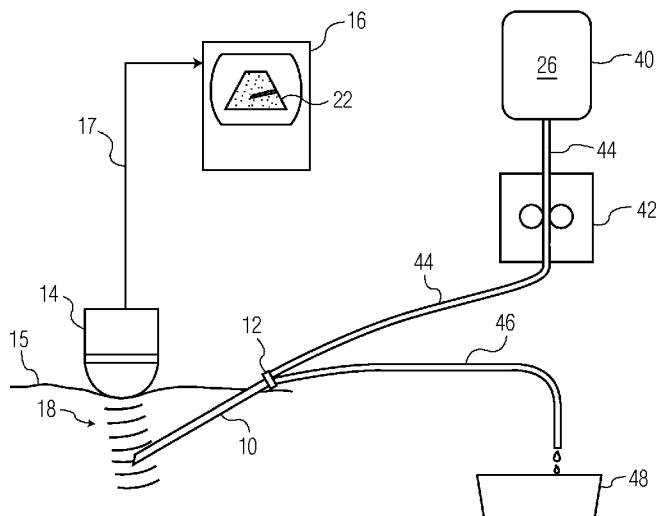


FIG. 4

(57) Abstract: An invasive medical device (20) includes a fluid path of microbubbles (26) which is imaged by ultrasound during use of the device. The fluid path extends through the device, preferably to the distal end of the device, so that the diffuse reflection of ultrasound from the microbubbles can be received to image the location of the device. The fluid path can be open, terminating at the tip of the device, or can be a closed path of a circulating microbubble fluid used for imaging and/or cooling.

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- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

Published:

- *with international search report*

-1-

ULTRASONIC VISUALIZATION OF PERCUTANEOUS NEEDLES,
INTRAVASCULAR CATHETERS AND OTHER INVASIVE DEVICES

This invention relates to medical diagnostic
5 ultrasonic imaging and, in particular, to ultrasonic
imaging of invasive devices inserted into the body
during a medical procedure.

Many invasive procedures are augmented by
noninvasive imaging, particularly when an invasive
10 device is inserted into the body to treat a target
tissue. For instance, a biopsy needle is often
visually assisted by ultrasound so that a target
tissue or cell mass is accessed directly and
positively by the needle. The clinician can visually
15 observe the path of the needle as it is inserted into
the body to sample or remove suspect pathology inside
the body. Another example is an r.f. ablation
needle, which is inserted into the body to engage a
tumor which is to be grasped or surrounded by the
20 tines of the needle before r.f. energy is applied.
The visualization assures that the needle tines have
correctly and fully engaged the tumor. A further
example is an intravascular catheter, which may be
guided over long distances inside the body from its
25 access point at a femoral artery, for instance. The
tip of the catheter may be observed by ultrasonic
imaging to assure its accurate placement in a
targeted chamber of the heart, for example.

However, it can often be difficult to clearly
30 visualize an invasive device in an ultrasound field.
Invasive devices like needles are generally inserted
into the body in close proximity to the ultrasound
probe. These solid instruments are specular
reflectors which present a shallow angle of incidence
35 to the ultrasound beams from the probe. Many times

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the position of the instrument is virtually parallel to the beam directions. Consequently the sound waves can be reflected deeper into the body rather than providing a strong return signal. As a result the
5 device will present a broken or indistinct appearance in the ultrasound image. Attempts have been made to mitigate this problem such as forming a diffraction grating near the tip of a needle as described in US Pat. 4,401,124 (Guess et al.), but this approach is also angle-dependent. Another approach is to Doppler demodulate the motion of the needle as described in
10 US Pat. 5,095,910 (Powers), but this technique is only effective while the needle is moving.
Accordingly it is desirable to be able to clearly
15 image an invasive instrument with ultrasound regardless of its position in the sound field.

In accordance with the principles of the present invention, an invasive medical instrument which is to be imaged by ultrasound utilizes a fluid of
20 microbubbles for improved visualization. Microbubbles are encapsulated gaseous particles or gaseous pre-cursors suspended in fluid. The microbubbles can be very small, on the order of tens of microns, and carried in saline or other fluids.
25 The fluid can be continuously flowing or circulated through the instrument in a closed path, or can exit the distal end of the instrument to enable the tip of the device to be clearly located in the image. The microbubbles in the fluid present diffuse reflectors to the impinging ultrasound waves, enabling the
30 device to be clearly imaged regardless of its position in the ultrasound field.

In the drawings:
FIGURE 1 is a cross-sectional view of an
35 invasive medical device with an open microbubble

fluid path constructed in accordance with the principles of the present invention.

FIGURE 1a is an enlarged view of the tip of the needle of FIGURE 1 showing the needle tip surrounded by microbubbles.
5

FIGURE 2 is a cross-sectional view of an invasive medical instrument with a closed loop microbubble fluid path circulating fluid to and from the tip of the instrument.

10 FIGURE 2a is a cross-sectional view of the needle sheath of FIGURE 2 showing the path connecting the supply and return fluid paths.

15 FIGURE 3 is a cross-sectional view of an r.f. ablation needle with the needle tines ultrasonically illuminated with a flow of microbubbles.

FIGURE 4 is a block diagram of an ultrasonic imaging system adapted to image microbubbles associated with an invasive medical device.

20 FIGURE 5 is a flow chart illustrating exemplary steps in performing r.f. ablation with the needle of FIGURE 3 in accordance with the principles of the present invention.

Referring first to FIGURE 1, an invasive medical instrument, here shown as a biopsy needle 20, is
25 constructed in accordance with the principles of the present invention. The needle 20 comprises an outer sheath 21, sometimes referred to as the insertion needle, which is inserted into the body toward tissue which is to be biopsied or otherwise probed by the instrument. The outer sheath 21 carries a stylet or
30 needle or other tool 24. When the outer sheath 21 is inserted into the body in proximity to the tissue to be probed, the stylet 24 is extended to pierce the suspect tissue and acquire a sample or perform some
35 other operation on the tissue. In some procedures

the insertion needle is removed from the body while the stylet or tool 24 is left in place for subsequent manipulation.

In accordance with the principles of the present invention a flow 26 of a fluid containing microbubbles is supplied through the lumen of the needle. In this embodiment the fluid path is open at the distal tip of the insertion needle and the microbubble fluid can flow out of the tip of the insertion needle 21 and surround the tip of the stylet 24. The microbubble fluid may be any biocompatible fluid such as water or saline solution which contains gaseous particles. The gaseous particles may be air bubbles, encapsulated microbubbles, phase-converted nanoparticles, agitated saline, or ultrasonic contrast agent to name a few candidates. The microbubbles are high echogenic particles which provide relatively strong echo returns from impinging ultrasound waves. In comparison with a needle which is a specular reflector from which the strength of the returning echoes is highly angle-dependent, the spherical microbubbles or other particles will return a significant echo signal with little or no angle dependency. Thus the bath 26 of microbubbles which surrounds the tip of the needle 24 will illuminate the tip location and the shaft of the needle and stylet regardless of the angle of the needle. The needle, on the other hand, may cause impinging ultrasound to glance off at the angle of the needle and scatter deeper into the tissue rather than return to the ultrasound transducer, resulting in dropout and an irregular appearance of the needle and stylet in the ultrasound image. This difficulty is resolved by the microbubble fluid path which returns

ultrasound from along the length of the needle with little or no angle dependency or image dropout.

FIGURE 1a is an enlarged view of the tip of the stylet 24, which illustrates the microbubbles 26 surrounding the tip of the instrument. The echo returns from the microbubbles 26 will thus illuminate the location of the tip in the ultrasound image.

FIGURE 2 illustrates another embodiment of the present invention in cross-section. The medical instrument illustrated in this embodiment has a closed fluid path for the microbubble solution. Such an embodiment is suitable for a catheter or other device which is inserted into the vasculature of the body, and also for instruments which utilize a cooling fluid for the tip of the instrument, in which case the cooling fluid will contain the microbubbles. An r.f. ablation catheter used to ablate the endocardial wall of the heart in cardiac resynchronization therapy may also have a fluid path suitable for carrying a microbubble solution in accordance with the present invention. In the example of FIGURE 2 the outer sheath 21 contains the microbubble fluid 26 in a supply fluid path 28a. The microbubble fluid 26 in this path 28a travels to the tip of the instrument from a source of supply as indicated by arrow 27. On the other side of the sheath 21 is a return fluid path 28b, through which the microbubble fluid returns to a point outside the instrument as indicated by the arrow 29. Near the tip of the sheath is a connecting path 28c through which fluid flows from the supply path 28a to the return path 28b, as shown in FIGURE 2a. An advantage of a closed fluid path instrument is that the microbubble fluid does not have to meet the stringent requirements of a fluid which is injected into the

body from an open fluid path instrument.

FIGURE 3 illustrates an example of an r.f. ablation needle 30 constructed in accordance with the principles of the present invention for treating tumors with radio frequency energy. In this example the needle sheath 21 carries an r.f. ablation needle with many small, curved tines 32a,32b at the distal tip. The needle sheath 21 is inserted into the body until the distal end of the sheath approaches a tumor which is to be treated. The needle is then deployed by extending the needle from the end of the sheath as shown in FIGURE 3. As the needle is deployed the many curved tines 32a,32b, etc. are disposed uniformly through the volume of the tumor. However, variations in the density or stiffness of the tumor tissue can cause the small tines to deflect from their intended paths and be non-uniformly distributed in the tumor. The clinician will check for this problem by imaging the deployed tines with ultrasound. However, as is apparent, the curved tines 32a,32b will scatter ultrasound at many angles, which can cause dropout and an indistinct view of the fine needle tines in the ultrasound image. In accordance with the principles of the present invention, a microbubble fluid 26 surrounds the needle inside the shaft 21 and will travel through the apertures in the tumor pierced by the tines as shown in FIGURE 3. The echo returns from the microbubbles adjacent the needle tines 32a,32b will not be angle dependent and will enable the fine tines of the r.f. ablation needle to be clearly visualized in the ultrasound image.

FIGURE 4 illustrates an invasive medical device 10 and an ultrasound system 14,16 constructed in accordance with the principles of the present

invention. In this example a needle 10 is inserted through the surface 15 of the body toward a target pathology. As the needle 10 is inserted its progress is monitored by an ultrasound probe 14 which
5 transmits ultrasound waves 18 to the needle and receives returning echoes for image formation. The transduced echo signals are coupled by a cable 17 to the mainframe 16 of the ultrasound system for processing and display. The echo signals are
10 processed to produce an ultrasound image 22 which shows the location of the needle in the body.

In accordance with the principles of the present invention, a bag 40 contains a microbubble fluid 26. The microbubble fluid is supplied to a fluid coupling 12 of the needle 10 by a tube 44. A pump 42 such as an infusion pump or roller pump will gently pump the microbubble fluid from the supply bag 40 to the needle. The pump pressure need be only sufficient to cause the microbubble fluid to reach the tip of the
15 needle, and to enable passage alongside a deployed tool through the aperture cut by the tool, such as the tines of an r.f. ablation needle. Thus, the fluid pressure need only be sufficient to overcome the occluding pressure of the tissue which surrounds
20 the tines, for example. In this example a return tube 46 is coupled to the fluid coupling 12 through which returning fluid is expelled into a container 48 for disposal. A return tube will be desirable for a closed path system when the microbubble fluid is
25 continuous supplied to the tip of the instrument as for cooling, for example. A return tube may also be desirable for an open path system in which a supply of fresh microbubble fluid is continuously supplied to the instrument.
30

35 In other embodiments the microbubble fluid bag

26 and the pump 42 may comprise a syringe pump with
the microbubble fluid contained within a syringe
which is operated by the syringe pump. The
microbubble fluid can be supplied by the pump system
5 which is a part of an r.f. ablation device or by any
other pumping or irrigation subsystem that is part of
the invasive device. The flow of microbubble fluid
may be controlled by the ultrasonic imaging system,
which controls the delivery of fluid for improved
10 imaging, either with or without operator involvement.
For example, automatic, semi-automatic or manual
image analysis may detect a poor image of the
invasive device and call for a greater or pre-
determined (e.g., a pulsatile flow) delivery of
15 microbubble fluid.

FIGURE 5 is an example of a procedure for using
an r.f. needle in accordance with the present
invention. In step 50 a catheter or r.f. needle is
inserted into an initial position adjacent to target
20 tissue. In the case of an r.f. ablation procedure
the needle tines are deployed into the tumor. An
infusion pump is then operated in step 52 to fill the
catheter or needle, and/or the space in the tissue
adjacent the deployed instrument, with the
25 microbubble fluid. Ultrasonic imaging is then
performed in step 54 in an imaging mode which
illuminates the microbubbles in the image such as
contrast-specific imaging, B-mode imaging, or Doppler
imaging. In step 56 the ultrasound images are
30 presented to the clinician performing the procedure.
The images can be 2d images or 3d images (desirable
for seeing the deployed tines of an r.f. ablation
needle) and the microbubble visualization images can
be overlaid on a structural B-mode image or shown
35 side-by-side. Additional post-processing may be

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performed as desired to highlight needle tines such as speckle-reduction processing. After viewing the location of the needle, catheter, or needle tines with the microbubble fluid, the clinician may adjust
5 the position of the invasive instrument as indicated in step 58. Once the instrument has been adjusted to its most beneficial and effective position in the body, the intended treatment is performed in step 60.

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WHAT IS CLAIMED IS:

1. An ultrasonic diagnostic imaging system for imaging an invasive medical device comprising:
 - 5 an invasive medical device having a fluid path;
 - a source of microbubble fluid coupled to the fluid path and providing microbubble fluid for the fluid path;
 - 10 an ultrasound probe scanning an ultrasonic image field which includes the location of the invasive medical device; and
 - 15 an ultrasound imaging system, coupled to the ultrasound probe and responsive to ultrasound signals received by the probe from the microbubbles of the fluid for displaying an image of the location of the microbubbles.
2. The ultrasonic diagnostic imaging system of Claim 1, wherein the fluid path extends to the distal tip of the medical device.
3. The ultrasonic diagnostic imaging system of Claim 1, wherein the medical device further includes an insertion portion and a tool which is extendable from the distal end of the insertion portion,
 - 25 wherein the fluid path extends to the distal end of the insertion portion and is open to the tool location.
- 30 4. The ultrasonic diagnostic imaging system of Claim 1, wherein the medical device further includes an insertion portion having a distal end,
 - wherein the fluid path further includes a supply path extending to the distal end and a return path extending from the distal end.

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5. The ultrasonic diagnostic imaging system of
Claim 4, wherein the fluid path further comprises a
connecting path which connects the supply path and
the return path at the distal end of the insertion
portion.

10 6. The ultrasonic diagnostic imaging system of
Claim 5, wherein the supply path, the connecting
path, and the return path further comprise a closed
loop path which supplies the microbubble fluid to the
distal end of the insertion portion and returns the
microbubble fluid from the distal end without passage
of the fluid into the body of a patient.

15

7. The ultrasonic diagnostic imaging system of
Claim 6, wherein the microbubble fluid further
comprises a fluid for the transport of heat from the
distal end of the insertion portion.

20

8. The ultrasonic diagnostic imaging system of
Claim 1, wherein the invasive medical device
comprises a catheter.

25

9. The ultrasonic diagnostic imaging system of
Claim 1, wherein the invasive medical device further
comprises an r.f. ablation device for one of applying
r.f. energy to a tumor or r.f. energy to a chamber of
the heart.

30

10. An ultrasonic diagnostic imaging system for
imaging an invasive medical device comprising:

an invasive medical device having a fluid path
and a coupling to the fluid path;

35

a source of microbubble fluid;

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a fluid pump coupled between the source of microbubble fluid and the medical device coupling which act to supply microbubble fluid to the fluid path of the device;

5 a return fluid path coupled to the medical device coupling for removal of microbubble fluid from the medical device;

10 an ultrasound probe which acts to scan an image field including the location of the invasive medical device within a body; and

15 an ultrasonic imaging system, coupled to the ultrasound probe, which produces an image of the location of the invasive medical device within the body.

11. The ultrasonic diagnostic imaging system of Claim 10, wherein a distal end of the invasive medical device is inserted into tissue, and

20 wherein the fluid path is open to allow microbubble fluid to flow to the tissue.

12. The ultrasonic diagnostic imaging system of Claim 10, wherein the fluid path of the invasive medical device extends to a distal end of the invasive medical device,

25 wherein the fluid path is a closed fluid path within the portion of the medical device that is insertable into tissue.

30 13. The ultrasonic diagnostic imaging system of Claim 10, wherein the fluid pump further comprises a syringe pump.

35 14. The ultrasonic diagnostic imaging system of Claim 10, wherein the microbubbles of the microbubble

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fluid further comprise one of air bubbles, encapsulated microbubbles, phase-converted nanoparticles, agitated saline, or ultrasonic contrast agent.

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15. The ultrasonic diagnostic imaging system of Claim 10, wherein the ultrasonic imaging system is operable to control the delivery of microbubble fluid by the fluid pump.

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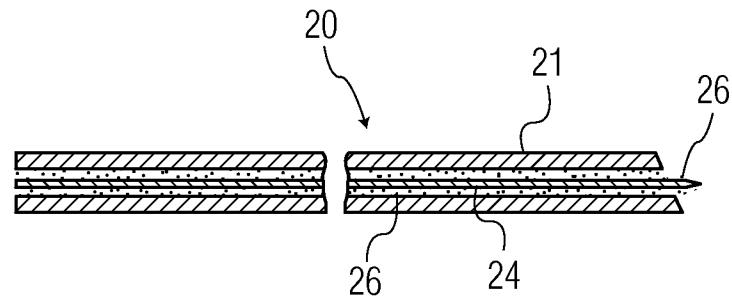


FIG. 1

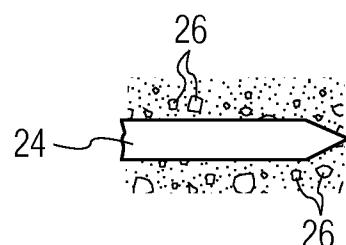


FIG. 1a

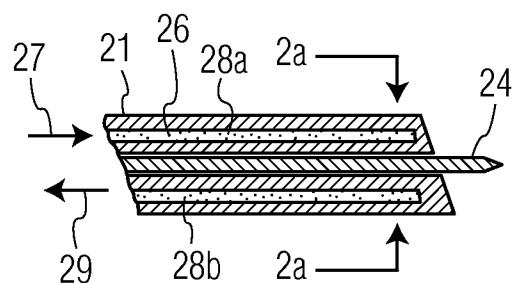


FIG. 2

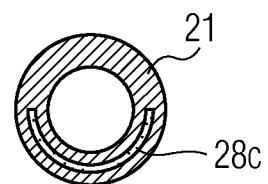


FIG. 2a

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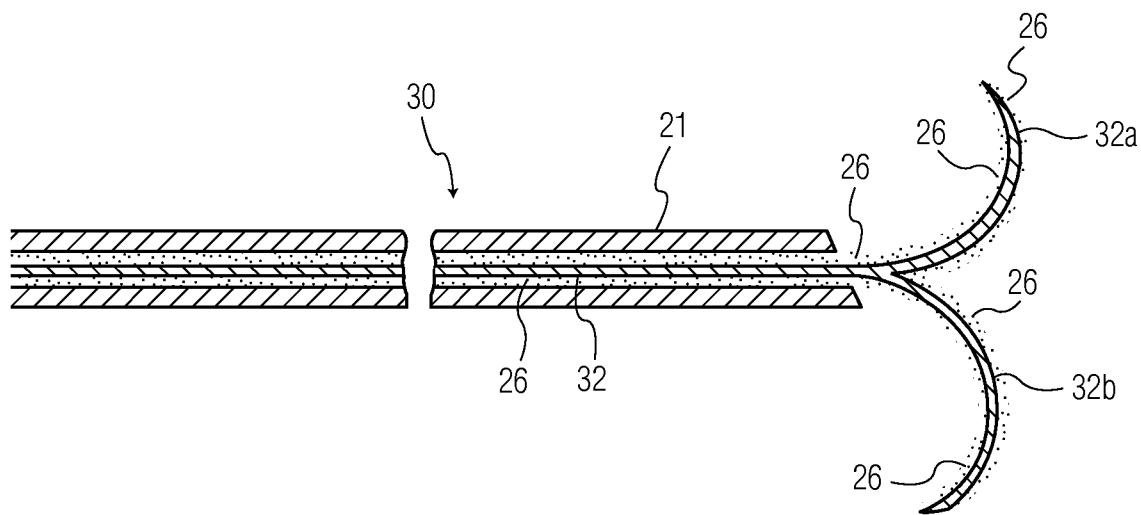


FIG. 3

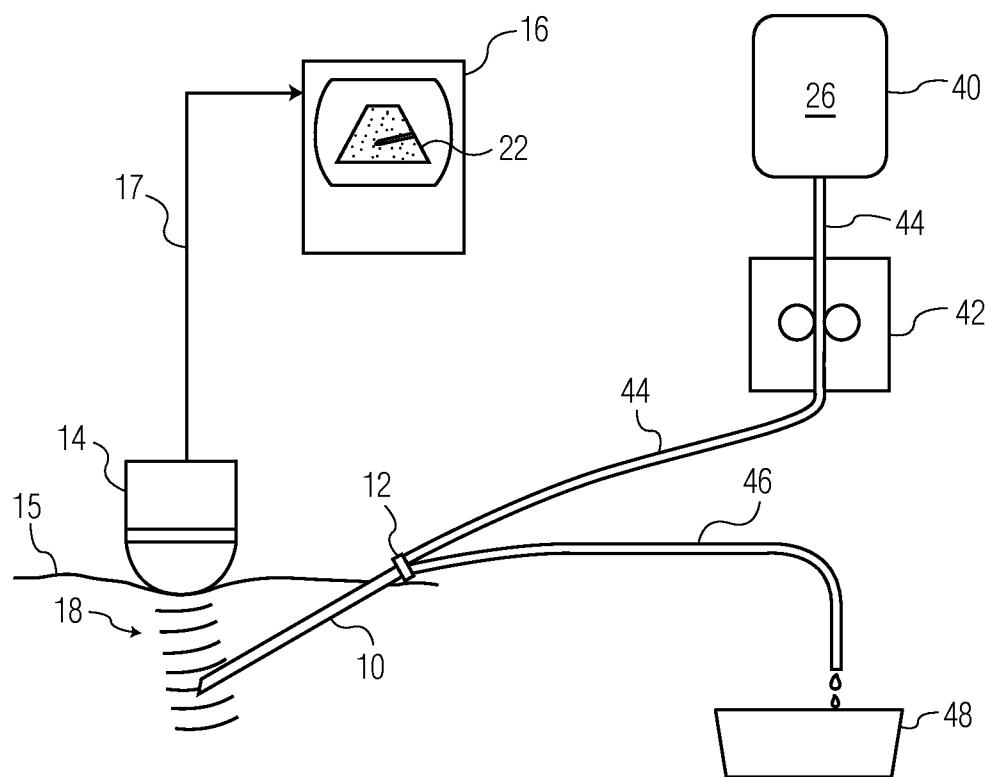


FIG. 4

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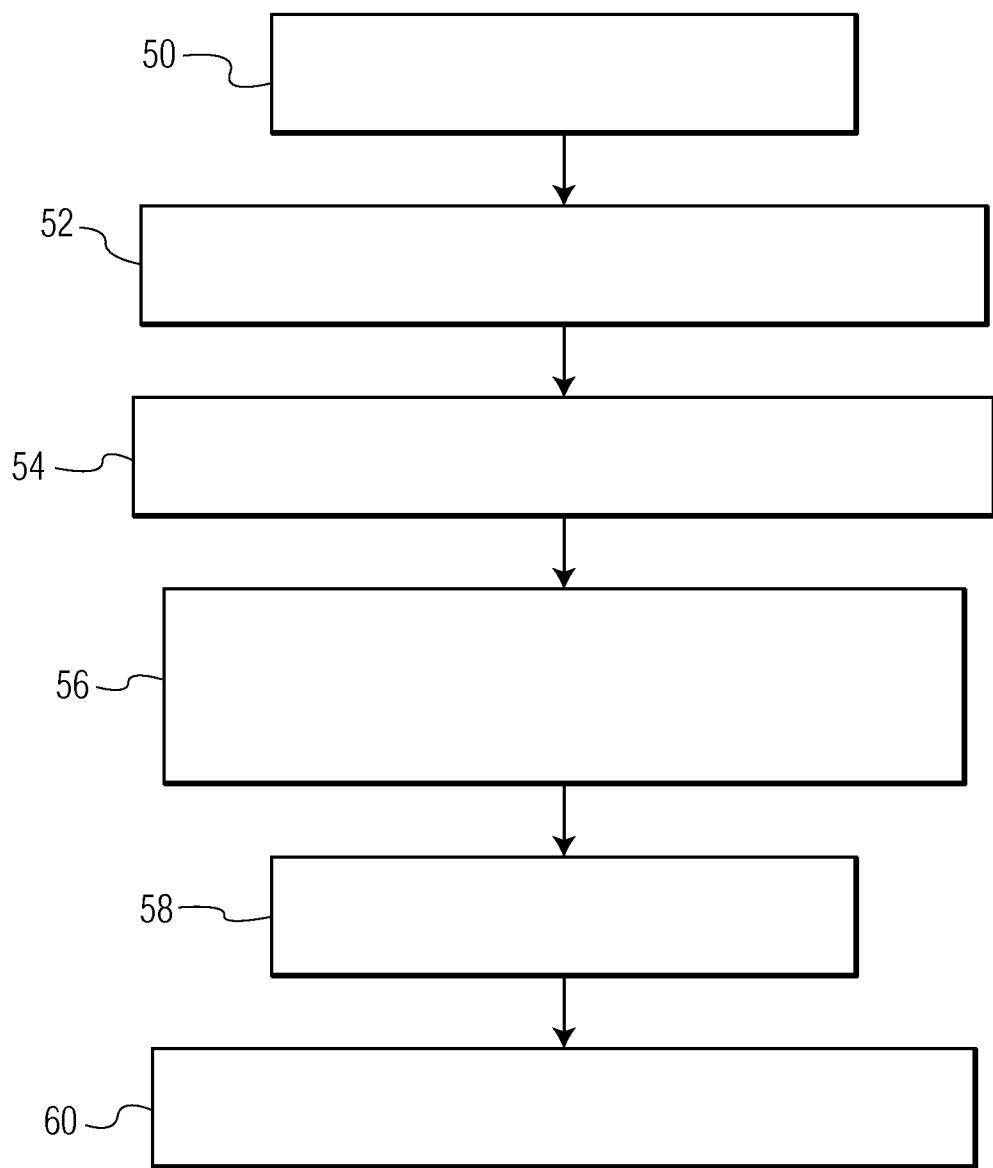


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2008/054843

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B8/08 A61B8/00
ADD. A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 2004/082749 A (KEENAN JAMES [CA]) 30 September 2004 (2004-09-30)</p> <p>abstract page 11, lines 20-22 page 12, lines 13-18 page 13, line 4 - page 14, line 2 page 15, lines 1-3 page 23, lines 5-10 page 24, columns 1-2 page 25, lines 5-7 figures 1,9B</p> <p>----- -/-</p>	1-15

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
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- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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- *&* document member of the same patent family

Date of the actual completion of the international search

27 April 2009

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INTERNATIONAL SEARCH REPORT

International application No PCT/IB2008/054843

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 94/03110 A (RAMMLER DAVID H [US]) 17 February 1994 (1994-02-17) abstract page 3, lines 13-30 page 5, line 34 – page 6, line 25 page 8, lines 1-11 page 11, lines 4-6 figure 1 -----	1-15
A	US 4 805 628 A (FRY FRANCIS J [US] ET AL) 21 February 1989 (1989-02-21) abstract column 3, line 34 – column 5, line 9 figures -----	1-15
A	US 2004/138566 A1 (CRAWFORD KELLAR EWEN JAMES [GB] ET AL KELLAR EWEN JAMES CRAWFORD [GB]) 15 July 2004 (2004-07-15) abstract figures 1-8 -----	1-15

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2008/054843

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		EP 0606467	A1	20-07-1994
		JP 6511413	T	22-12-1994
		US 5327891	A	12-07-1994
US 4805628	A 21-02-1989	NONE		
US 2004138566	A1 15-07-2004	NONE		

专利名称(译)	经皮针，血管内导管和其他侵入性装置的超声可视化		
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当前申请(专利权)人(译)	皇家飞利浦电子N.V.		
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IPC分类号	A61B8/08 A61B8/00 A61B19/00		
CPC分类号	A61B8/0841 A61B8/0833 A61B8/463 A61B8/481 A61B8/483 A61B18/1477 A61B18/1492 A61B2017/3413 A61B2018/00011 A61B2018/1425 A61B2090/3925 A61B2090/3933		
优先权	60/990638 2007-11-28 US		
外部链接	Espacenet		

摘要(译)

侵入式医疗装置 (20) 包括微泡 (26) 的流体路径，其在装置的使用期间通过超声成像。流体路径延伸穿过装置，优选地延伸到装置的远端，使得可以接收来自微泡的超声波的漫反射以对装置的位置进行成像。流体路径可以是开放的，终止于装置的尖端，或者可以是用于成像和/或冷却的循环微泡流体的闭合路径。